Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC) (repealed)

Article 1

[F1 1 A ‘cosmetic product’ shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.**]**

2 The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.

[F2 3 Cosmetic products containing one of the substances listed in Annex V shall be excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to those products.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F2 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

*[*F1 *Article 2*

A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

Article 3

Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.

*[*F3 *Article 4*

1 Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

a substances listed in Annex II;

b substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;**]**

[F2c colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

d colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;**]**

[F3e preservatives other than those listed in Annex VI, Part 1;

f preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product;**]**

[F4g UV filters other than those listed in Part 1 of Annex VII;

h UV filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein**[**F5.**]]**

[F6**[**F1(i)**]]** F6. . . . . .

[F32 The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F2 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

F3 Inserted by Council Directive of 17 May 1982 (82/368/EEC).

F4 Inserted by Council Directive of 26 October 1983 (83/574/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

F6 Deleted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

[F7Article 4a

1 Without prejudice to the general obligations deriving from Article 2, Member States shall prohibit:

a the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

b the marketing of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Directive, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

c the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;

d the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in Annex V to Council Directive 67/548/EEC of 27 June 1967 on

the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[1]or in Annex IX to this Directive.

No later than 11 September 2004 the Commission shall, in accordance with the procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) establish the contents of Annex IX.

2 The Commission, after consultation of the SCCNFP and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, shall establish timetables for the implementation of the provisions under paragraph 1(a), (b) and (d), including deadlines for the phasing-out of the various tests. The timetables shall be made available to the public not later than 11 September 2004 and be sent to the European Parliament and the Council. The period for implementation shall be limited to a maximum of six years after the entry into force of Directive 2003/15/EC in relation to paragraph 1(a), (b) and (d).

2.1 In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to a maximum of 10 years after the entry into force of Directive 2003/15/EC.

2.2 The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies should form part of the yearly reports presented pursuant to Article 9.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 may be adapted within a maximum time limit of six years as referred to in paragraph 2 or 10 years as referred to in paragraph 2.1 and after consultation of the entities referred to in paragraph 2.

2.3 The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies should form part of the yearly reports presented pursuant to Article 9. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in paragraph 2.1, that for technical reasons one or more tests referred to in paragraph 2.1 will not be developed and validated before the expiry of the period referred to in paragraph 2.1 it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

2.4 In exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consultation of the SCCNFP and by means of a reasoned decision, authorise the derogation in accordance with the procedure referred to in Article 10(2). This authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall only be granted if:

a the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function;

b the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research Protocol proposed as the basis for the evaluation.

The decision on the authorisation, the conditions associated with it and the final result achieved shall be part of the annual report to be presented by the Commission in accordance with Article 9.

3 For the purposes of this Article:

a 'finished cosmetic product' means the cosmetic product in its final formulation, as placed on the market and made available to the final consumer, or its prototype.

b 'prototype' means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed.

Textual Amendments

F7 Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

Article 4b

The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.**]**

Textual Amendments

F7 Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

[F2*Article 5*

Member States shall allow the marketing of cosmetic products containing:

(a) the substances listed in Annex III, Part 2, within the limits and under the conditions laid down, up to the dates in column (g) of that Annex;

(b) the colouring agents listed in Annex IV, Part 2, within the limits and under the conditions laid down, until the admission dates given in that Annex;

(c) the preservatives listed in Annex VI, Part 2, within the limits and under the condition laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product;

(d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

At these dates, these substances, colouring agents, preservatives and UV filters shall be:

— definitively allowed, or
— definitively prohibited (Annex II), or
— maintained for a given period specified in Part 2 of Annexes III, IV, VI and VII, or
— deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.**]**

Textual Amendments
F2 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

[F1 Article 5a

1 No later than 14 December 1994 the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.

For the purposes of this Article, 'cosmetic ingredient' shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.

2 The inventory shall contain informtion on:
— the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organization, the Einecs, Iupac, CAS and colour index numbers, and the common name referred to in Article 7 (2),
— the usual function(s) of the ingredient in the final product,
— where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.

3 The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.**]**

Textual Amendments
F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

[F2 Article 6

[F1 Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone:**]**

a the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community;

b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

[F5 c the date of minimum durability shall be indicated by the words: 'best used before the end of' followed by either:

— the date itself, or

— details of where it appears on the packaging.

The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol given in Annex VIIIa followed by the period (in months and/or years);**]]**

[F1 d particular precautions to be observed in use, especially those listed in the column 'Conditions of use and warnings which must be printed on the label' in Annexes III, IV, VI and VII, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging;**]**

[F2 e the batch number of manufacture or the reference for identifying the goods. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;**]**

[F1 f the function of the product, unless it is clear from the presentation of the product;

[F5 g a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word 'ingredients'. Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.

The following shall not, however, be regarded as ingredients:

— impurities in the raw materials used,

— subsidiary technical materials used in the preparation but not present in the final product,

— materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

Perfume and aromatic compositions and their raw materials shall be referred to by the word 'perfume' or 'aroma'. However, the presence of substances, the mention of which is required under the column 'other limitations and requirements' in Annex III, shall be indicated in the list irrespective of their function in the product.

Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV. For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added.

An ingredient must be identified by the common name referred to in Article 7(2) or, failing that, by one of the names referred to in Article 5a(2), first indent.

In accordance with the procedure referred to in Article 10(2), the Commission may adapt the criteria and conditions set out in Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products[(2)] under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.**]**

Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached to the cosmetic product.

In the case of soap, bath balls and other small products where it is impraticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.**]**

[[F2]2 For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

3 Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have.**[**[F6]**[**[F1]Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.**]]**

[[F7]Furthermore, the manufacturer or the person responsible for placing the product on the Community market may take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products. Guidelines shall be adopted in accordance with the procedure referred to in Article 10(2) and published in the *Official Journal of the European Union*. The European Parliament shall receive copies of the draft measures submitted to the Committee.**]]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F2 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

F6 Deleted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

F7 Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

Article 7

1 Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.

[F1 2 They may, however, require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.

3 Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.

Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

Article 7a

1 The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):

a the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

b the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

c the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance

with the legislation and practice of the Member State which is the place of manufacture or first importation;

[F5 d assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There shall be *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible;**]**

e the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;

f existing data on undesirable effects on human health resulting from use of the cosmetic product;

g proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product**[**F5;**]**

[F7 h data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of non-member countries.

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.**]**

2 The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances[(3)].

3 The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4 The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5 Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

The Member States shall ensure that the abovementioned authorities continue to cooperate in areas where such cooperation is necessary to the smooth application of this Directive.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

F7 Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

[F3 Article 8

1 In accordance with the procedure laid down in Article 10 the following shall be determined:

— the methods of analysis necessary for checking the composition of cosmetic products,

— the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.**]**

[F1 2 The common nomenclature of ingredients used in cosmetic products and, after consultation of the **[**F5 Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers**]**, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F3 Inserted by Council Directive of 17 May 1982 (82/368/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

[F3 Article 8a

1 Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

a the authorization must be limited to a maximum period of three years;

b the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;

c cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2 The Member Stats shall forward to the Commission and to the other Member States the next of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3 Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the **[**F5Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers**]** and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.**]**

Textual Amendments

F3 Inserted by Council Directive of 17 May 1982 (82/368/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

*I*F5*Article 9*

Every year the Commission shall present a report to the European Parliament and the Council on:

(a) progress made in the development, validation and legal acceptance of alternative methods. The report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[(4)]. The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;

(b) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by non-member countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries;

(c) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Textual Amendments

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

Article 10

1 The Commission shall be assisted by the Standing Committee on Cosmetic Products.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.**]**

Textual Amendments

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

Article 11

Without prejudice to Article 5 and not later than one year after expiry of the period laid down in Article 14 (1) for implementation of this Directive by the Member States, the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances.

Article 12

1 If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

[F2 2 The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.**]**

3 If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

Textual Amendments

F2 Inserted by Council Directive of 21 December 1988 (88/667/EEC).

Article 13

Precise reasons shall be stated for any individual measures placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Directive. It shall be notified to the party concerned together with particulars of the remedies available to him under the laws in force in the Member States and of the time limits allowed for the exercise of such remedies.

Article 14

1 Member States shall bring into force the provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

2 Member States may, however, for a period of 36 months from notification of this Directive, authorize the marketing in their territory of cosmetic products which do not conform to the requirements of the Directive.

3 Member States shall ensure that the texts of such provisions of national law as they adopt in the field governed by this Directive are communicated to the Commission.

Article 15

This Directive is addressed to the Member States.

(1) **[**[F7]OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1)**.]**

(2) **[**[F1]**[**[F5]OJ L 140, 23.6.1995, p. 26.**]]**

(3) **[**[F1]OJ No L 15, 17. 1. 1987, p. 29.**]**

(4) **[**[F5]OJ L 358, 18.12.1986, p. 1.**]**

Textual Amendments

F1 Inserted by Council Directive of 14 June 1993 (93/35/EEC).

F5 Substituted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).

F7 Inserted by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Text with EEA relevance).